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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA**

PAUL GALVAN,

Plaintiff,

v.

MONSANTO COMPANY,

Defendant.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

INTRODUCTION

1
2 1. In 1970, Defendant Monsanto Company, Inc. (“Monsanto”)
3 discovered the herbicidal properties of glyphosate and began marketing it in
4 products in 1974 under the brand name Roundup[®]. Roundup[®] is a non-selective
5 herbicide used to kill weeds that commonly compete with the growing of crops. In
6 addition to the active ingredient glyphosate, Roundup[®] contains the surfactant
7 Polyethoxylated tallow amine (POEA) and/or adjuvants and other so-called “inert”
8 ingredients. In 2001, glyphosate was the most-used pesticide active ingredient in
9 American agriculture with 85–90 million pounds used annually. That number grew
10 to 185 million pounds in 2007.¹ As of 2013, glyphosate was the world’s most
11 widely used herbicide.

12 2. Monsanto is a multinational agricultural biotechnology corporation
13 based in St. Louis, Missouri, and incorporated in Delaware. It is the world's
14 leading producer of glyphosate. As of 2009, Monsanto was the world’s leading
15 producer of seeds, accounting for 27% of the world seed market.² The majority of
16

17 ¹ Arthur Grube et al., U.S. Env'tl. Prot. Agency, *Pesticides Industry Sales*
18 *and Usage, 2006–2007 Market Estimates* 14 (2011), available at
http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf.

19 ² ETC Group, *Who Will Control the Green Economy?* 22 (2011), available
20 at

1 these seeds are of the Roundup Ready[®] brand. The stated advantage of Roundup
2 Ready[®] crops is that they substantially improve a farmer's ability to control
3 weeds, because glyphosate can be sprayed in the fields during the growing season
4 without harming the crops. In 2010, an estimated 70% of corn and cotton and
5 90% of soybean fields in the United States were Roundup Ready[®].³

6 3. Monsanto's glyphosate products are registered in 130 countries and
7 approved for use on over 100 different crops.⁴ They are ubiquitous in the
8 environment. Numerous studies confirm that glyphosate is found in rivers,
9 streams, and groundwater in agricultural areas where Roundup[®] is used.⁵ It has

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12 http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf.

13 ³ William Neuman & Andrew Pollack, *Farmers Cope With Roundup-*
14 *Resistant Weeds*, N.Y. TIMES, May 3, 2010, available at
15 [http://www.nytimes.com/2010/05/04/business/energy-](http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewan)
16 [environment/04weed.html?pagewan](http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewan).

17 ⁴ Monsanto, *Backgrounder-History of Monsanto's Glyphosate Herbicides*
18 (Sep. 2, 2015), [http://www.monsanto.com/products/documents/glyphosate-](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf)
19 [background-materials/back_history.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf).

20 ⁵ See U.S. Geological Survey, *USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin* (2011), available at <http://www.usgs.gov/newsroom/article.asp?ID=2909>; see also U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, available at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf>.

1 been found in food,⁶ in the urine of agricultural workers,⁷ and even in the urine of
2 urban dwellers who are not in direct contact with glyphosate.⁸

3 4. On March 20, 2015, the International Agency for Research on Cancer
4 (“IARC”), an agency of the World Health Organization (“WHO”), issued an
5 evaluation of several herbicides, including glyphosate. That evaluation was based,
6 in part, on studies of exposures to glyphosate in several countries around the
7 world, and it traces the health implications from exposure to glyphosate since
8 2001.

9 5. On July 29, 2015, IARC issued the formal monograph relating to
10 glyphosate. In that monograph, the IARC Working Group provides a thorough
11

12 ⁶ Thomas Bohn et al., *Compositional Differences in Soybeans on the*
13 *Market: Glyphosate Accumulates in Roundup Ready GM Soybeans*, 153 FOOD
14 CHEMISTRY 207 (2013), available at
<http://www.sciencedirect.com/science/article/pii/S0308814613019201>.

15 ⁷ John F. Acquavella et al., *Glyphosate Biomonitoring for Farmers and*
16 *Their Families: Results from the Farm Family Exposure Study*, 112(3) ENVTL.
17 HEALTH PERSPECTIVES 321 (2004), available at
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/>; Kathryn Z. Guyton et
al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon &*
Glyphosate, 112 IARC Monographs 76, section 5.4 (2015), available at
[http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8).

18 ⁸ Dirk Brändli & Sandra Reinacher, *Herbicides found in Human Urine*, 1
19 ITHAKA JOURNAL 270 (2012), available at [http://www.ithaka-](http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf)
[journal.net/druckversionen/e052012-herbicides-urine.pdf](http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf).

1 review of the numerous studies and data relating to glyphosate exposure in
2 humans.

3 6. The IARC Working Group classified glyphosate as a Group 2A
4 herbicide, which means that it is *probably carcinogenic to humans*. The IARC
5 Working Group concluded that the cancers most associated with glyphosate
6 exposure are non-Hodgkin lymphoma and other haematopoietic cancers, including
7 lymphocytic lymphoma / chronic lymphocytic leukemia, B-cell lymphoma, and
8 multiple myeloma.⁹

9 7. The IARC evaluation is significant. It confirms what has been
10 believed for years: that glyphosate is toxic to humans.

11 8. Nevertheless, Monsanto, since it began selling Roundup[®], has
12 represented it as safe to humans and the environment. Indeed, Monsanto has
13 repeatedly proclaimed and continues to proclaim to the world, and particularly to
14 United States consumers, that glyphosate-based herbicides, including Roundup[®],
15 create no unreasonable risks to human health or to the environment.

16
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18 _____
19 ⁹ See Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion,*
20 *Malathion, Diazinon & Glyphosate, supra.*

JURISDICTION AND VENUE

9. Federal diversity jurisdiction in this Court is proper under 28 U.S.C. § 1332 because Plaintiff is a citizen of California, a different state than the Defendant's states of citizenship, and the aggregate amount in controversy exceeds \$75,000, exclusive of interest and costs.

10. This Court has personal jurisdiction over Monsanto Company ("Monsanto") because Monsanto knows or should have known that its Roundup[®] products are sold throughout the State of California, and, more specifically, caused Roundup[®] to be sold to Plaintiff in the State of California.

11. In addition, Monsanto maintains sufficient contacts with the State of California such that this Court's exercise of personal jurisdiction over it does not offend traditional notions of fair play and substantial justice.

12. Venue is proper within this District under 28 U.S.C. § 1391(b)(2) because Plaintiff was injured and diagnosed in this District. Further, Monsanto, as a corporate entity, is deemed to reside in any judicial district in which it is subject to personal jurisdiction.

1 form aromatic amino acids necessary for protein synthesis. Treated plants
2 generally die within two to three days. Because plants absorb glyphosate, it
3 cannot be completely removed by washing or peeling produce or by milling,
4 baking, or brewing grains.

5 18. For nearly 40 years, farms across the world have used Roundup®
6 without knowing of the dangers its use poses. That is because when Monsanto
7 first introduced Roundup®, it touted glyphosate as a technological breakthrough: it
8 could kill almost every weed without causing harm either to people or to the
9 environment. Of course, history has shown that not to be true. According to the
10 WHO, the main chemical ingredient of Roundup®—glyphosate—is a probable
11 cause of cancer. Those most at risk are farm workers and other individuals with
12 workplace exposure to Roundup®, such as garden center workers, nursery
13 workers, and landscapers. Agricultural workers are, once again, victims of
14 corporate greed. Monsanto assured the public that Roundup® was harmless. In
15 order to prove this, Monsanto has championed falsified data and has attacked
16 legitimate studies that revealed Roundup®'s dangers. Monsanto has led a
17 prolonged campaign of misinformation to convince government agencies, farmers
18 and the general population that Roundup® is safe.

1 *The Discovery of Glyphosate and Development of Roundup[®]*

2 19. The herbicidal properties of glyphosate were discovered in 1970 by
3 Monsanto chemist John Franz. The first glyphosate-based herbicide was
4 introduced to the market in the mid-1970s under the brand name Roundup[®].¹⁰
5 From the outset, Monsanto marketed Roundup[®] as a “safe” general-purpose
6 herbicide for widespread commercial and consumer use. It still markets
7 Roundup[®] as safe today.¹¹

8 20. In addition to the active ingredient glyphosate, Roundup[®]
9 formulations also contain adjuvants and other chemicals, such as the surfactant
10 POEA, which are considered “inert” and therefore protected as “trade secrets” in
11 manufacturing. Growing evidence suggests that these adjuvants and additional
12 components of Roundup[®] formulations are not, in fact, inert and are toxic in their
13 own right.

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17 ¹⁰ Monsanto, *Backgrounder, History of Monsanto’s Glyphosate Herbicide*
18 (Sep. 2, 2015), [http://www.monsanto.com/products/documents/glyphosate-](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf)
19 [background-materials/back_history.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf).

20 ¹¹ Monsanto, *What is Glyphosate?* (Sep. 2, 2015),
<http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf>.

Registration of Herbicides under Federal Law

21. The manufacture, formulation, and distribution of herbicides, such as Roundup[®], are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or “Act”), 7 U.S.C. § 136 *et seq.* FIFRA requires that all pesticides be registered with the Environmental Protection Agency (“EPA” or “Agency”) prior to their distribution, sale, or use, except as described by the Act. 7 U.S.C. § 136a(a).

22. Because pesticides are toxic to plants, animals, and humans, at least to some degree, the EPA requires as part of the registration process, among other things, a variety of tests to evaluate the potential for exposure to pesticides, toxicity to people and other potential non-target organisms, and other adverse effects on the environment. Registration by the EPA, however, is not an assurance or finding of safety. The determination the Agency must make in registering or re-registering a product is not that the product is “safe,” but rather that use of the product in accordance with its label directions “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D).

23. FIFRA defines “unreasonable adverse effects on the environment” to mean “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any

1 pesticide.” 7 U.S.C. § 136(bb). FIFRA thus requires EPA to make a risk/benefit
2 analysis in determining whether a registration should be granted or a pesticide
3 allowed to continue to be sold in commerce.

4 24. The EPA and the State of California registered Roundup[®] for
5 distribution, sale, and manufacture in the United States and the State of California.

6 25. FIFRA generally requires that the registrant, Monsanto in the case of
7 Roundup[®], conducts the health and safety testing of pesticide products. The EPA
8 has protocols governing the conduct of tests required for registration and the
9 laboratory practices that must be followed in conducting these tests. The data
10 produced by the registrant must be submitted to the EPA for review and
11 evaluation. The government is not required, nor is it able, however, to perform the
12 product tests that are required of the manufacturer.

13 26. The evaluation of each pesticide product distributed, sold, or
14 manufactured is completed at the time the product is initially registered. The data
15 necessary for registration of a pesticide has changed over time. The EPA is now
16 in the process of re-evaluating all pesticide products through a Congressionally-
17 mandated process called “re-registration.” 7 U.S.C. § 136a-1. In order to
18 reevaluate these pesticides, the EPA is demanding the completion of additional
19 tests and the submission of data for the EPA’s recent review and evaluation.

20

1 27. In the case of glyphosate, and therefore Roundup[®], the EPA had
2 planned on releasing its preliminary risk assessment—in relation to the
3 reregistration process—no later than July 2015. The EPA completed its review of
4 glyphosate in early 2015, but it delayed releasing the risk assessment pending
5 further review in light of the WHO’s health-related findings.

6 ***Scientific Fraud Underlying the Marketing and Sale of Glyphosate/Roundup[®]***

7 28. Based on early studies showing that glyphosate could cause cancer in
8 laboratory animals, the EPA originally classified glyphosate as *possibly*
9 *carcinogenic to humans* (Group C) in 1985. After pressure from Monsanto,
10 including contrary studies it provided to the EPA, the EPA changed its
11 classification to *evidence of non-carcinogenicity in humans* (Group E) in 1991. In
12 so classifying glyphosate, however, the EPA made clear that the designation did
13 not mean the chemical does not cause cancer: “It should be emphasized, however,
14 that designation of an agent in Group E is based on the available evidence at the
15 time of evaluation and should not be interpreted as a definitive conclusion that the
16 agent will not be a carcinogen under any circumstances.”¹²

17 ¹² U.S. Env’tl. Prot. Agency, *Memorandum, Subject: SECOND Peer Review*
18 *of Glyphosate 1* (1991), available at
19 [http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf)
20 [Oct-91_265.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf).

1 29. On two occasions, the EPA found that the laboratories hired by
2 Monsanto to test the toxicity of its Roundup[®] products for registration purposes
3 committed fraud.

4 30. In the first instance, Monsanto, in seeking initial registration of
5 Roundup[®] by the EPA, hired Industrial Bio-Test Laboratories (“IBT”) to perform
6 and evaluate pesticide toxicology studies relating to Roundup[®].¹³ IBT performed
7 about 30 tests on glyphosate and glyphosate-containing products, including nine
8 of the 15 residue studies needed to register Roundup[®].

9 31. In 1976, the United States Food and Drug Administration (“FDA”)
10 performed an inspection of IBT that revealed discrepancies between the raw data
11 and the final report relating to the toxicological impacts of glyphosate. The EPA
12 subsequently audited IBT; it too found the toxicology studies conducted for the
13 Roundup[®] herbicide to be invalid.¹⁴ An EPA reviewer stated, after finding

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15 ¹³ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories*
(Sep. 2, 2015), [http://www.monsanto.com/products/documents/glyphosate-](http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf)
16 [background-materials/ibt_craven_bkg.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf).

17 ¹⁴ U.S. Env'tl. Prot. Agency, *Summary of the IBT Review Program Office of*
Pesticide Programs (1983), available at
18 [http://nepis.epa.gov/Exe/ZyNET.exe/91014ULV.TXT?ZyActionD=ZyDocument](http://nepis.epa.gov/Exe/ZyNET.exe/91014ULV.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1981+Thru+1985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C81thru85%5CTxt%5C00000022%5)
19 [&Client=EPA&Index=1981+Thru+1985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C81thru85%5CTxt%5C00000022%5](http://nepis.epa.gov/Exe/ZyNET.exe/91014ULV.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1981+Thru+1985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C81thru85%5CTxt%5C00000022%5)
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1 “routine falsification of data” at IBT, that it was “hard to believe the scientific
2 integrity of the studies when they said they took specimens of the uterus from
3 male rabbits.”¹⁵

4 32. Three top executives of IBT were convicted of fraud in 1983.

5 33. In the second incident of data falsification, Monsanto hired Craven
6 Laboratories in 1991 to perform pesticide and herbicide studies, including for
7 Roundup[®]. In that same year, the owner of Craven Laboratories and three of its
8 employees were indicted, and later convicted, of fraudulent laboratory practices in
9 the testing of pesticides and herbicides.¹⁶

10 34. Despite the falsity of the tests that underlie its registration, within a
11 few years of its launch, Monsanto was marketing Roundup[®] in 115 countries.
12

13 C91014ULV.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h
14 %7C-
15 &MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y1
16 50g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=
ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&Seek
Page=x&ZyPURL.

17 ¹⁵ Marie-Monique Robin, *The World According to Monsanto: Pollution,*
18 *Corruption and the Control of the World's Food Supply* (2011) (citing U.S. Env'tl.
Prot. Agency, *Data Validation, Memo from K. Locke, Toxicology Branch, to R.*
Taylor, Registration Branch. Washington, D.C. (August 9, 1978)).

19 ¹⁶ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories,*
20 *supra.*

1 ***The Importance of Roundup® to Monsanto's Market Dominance Profits***

2 35. The success of Roundup® was key to Monsanto's continued
3 reputation and dominance in the marketplace. Largely due to the success of
4 Roundup® sales, Monsanto's agriculture division was out-performing its
5 chemicals division's operating income, and that gap increased yearly. But with its
6 patent for glyphosate expiring in the United States in the year 2000, Monsanto
7 needed a strategy to maintain its Roundup® market dominance and to ward off
8 impending competition.

9 36. In response, Monsanto began the development and sale of genetically
10 engineered Roundup Ready® seeds in 1996. Since Roundup Ready® crops are
11 resistant to glyphosate, farmers can spray Roundup® onto their fields during the
12 growing season without harming the crop. This allowed Monsanto to expand its
13 market for Roundup® even further; by 2000, Monsanto's biotechnology seeds
14 were planted on more than 80 million acres worldwide and nearly 70% of
15 American soybeans were planted from Roundup Ready® seeds. It also secured
16 Monsanto's dominant share of the glyphosate/Roundup® market through a
17 marketing strategy that coupled proprietary Roundup Ready® seeds with
18 continued sales of its Roundup® herbicide.

1 37. Through a three-pronged strategy of increasing production,
2 decreasing prices, and by coupling with Roundup Ready[®] seeds, Roundup[®]
3 became Monsanto's most profitable product. In 2000, Roundup[®] accounted for
4 almost \$2.8 billion in sales, outselling other herbicides by a margin of five to one,
5 and accounting for close to half of Monsanto's revenue.¹⁷ Today, glyphosate
6 remains one of the world's largest herbicides by sales volume.

7 ***Monsanto has known for decades that it falsely advertises the safety of Roundup[®]***

8 38. In 1996, the New York Attorney General ("NYAG") filed a lawsuit
9 against Monsanto based on its false and misleading advertising of Roundup[®]
10 products. Specifically, the lawsuit challenged Monsanto's general representations
11 that its spray-on glyphosate-based herbicides, including Roundup[®], were "**safer**
12 **than table salt**" and "**practically non-toxic**" to mammals, birds, and fish.
13 Among the representations the NYAG found deceptive and misleading about the
14 human and environmental safety of glyphosate and/or Roundup[®] are the
15 following:

16 a) "Remember that environmentally friendly
17 Roundup herbicide is biodegradable. It won't build up in

18 ¹⁷ David Barboza, *The Power of Roundup; A Weed Killer Is A Block for*
19 *Monsanto to Build On*, N.Y. TIMES, Aug. 2, 2001, available at
[http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-](http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html)
20 [killer-is-a-block-for-monsanto-to-build-on.html](http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html).

1 the soil so you can use Roundup with confidence along
2 customers' driveways, sidewalks and fences ..."

3 b) "And remember that Roundup is biodegradable
4 and won't build up in the soil. That will give you the
5 environmental confidence you need to use Roundup
6 everywhere you've got a weed, brush, edging or trimming
7 problem."

8 c) "Roundup biodegrades into naturally occurring
9 elements."

10 d) "Remember that versatile Roundup herbicide
11 stays where you put it. That means there's no washing or
12 leaching to harm customers' shrubs or other desirable
13 vegetation."

14 e) "This non-residual herbicide will not wash or
15 leach in the soil. It ... stays where you apply it."

16 f) "You can apply Accord with 'confidence because
17 it will stay where you put it' it bonds tightly to soil
18 particles, preventing leaching. Then, soon after
19 application, soil microorganisms biodegrade Accord into
20 natural products."

g) "Glyphosate is less toxic to rats than table salt
following acute oral ingestion."

h) "Glyphosate's safety margin is much greater
than required. It has over a 1,000-fold safety margin in
food and over a 700-fold safety margin for workers who
manufacture it or use it."

i) "You can feel good about using herbicides by
Monsanto. They carry a toxicity category rating of
'practically non-toxic' as it pertains to mammals, birds
and fish."

1 j) "Roundup can be used where kids and pets will
2 play and breaks down into natural material." This ad
3 depicts a person with his head in the ground and a pet dog
standing in an area which has been treated with
Roundup.¹⁸

4 39. On November 19, 1996, Monsanto entered into an Assurance of
5 Discontinuance with NYAG, in which Monsanto agreed, among other things, "to
6 cease and desist from publishing or broadcasting any advertisements [in New
7 York] that represent, directly or by implication" that:

8 a) its glyphosate-containing pesticide products or
9 any component thereof are safe, non-toxic, harmless or
free from risk.

10 * * *

11 b) its glyphosate-containing pesticide products or
12 any component thereof manufactured, formulated,
distributed or sold by Monsanto are biodegradable

13 * * *

14 c) its glyphosate-containing pesticide products or
15 any component thereof stay where they are applied under
16 all circumstances and will not move through the
environment by any means.

17 * * *

18 ¹⁸ Attorney General of the State of New York, In the Matter of Monsanto
19 Company, Assurance of Discontinuance Pursuant to Executive Law § 63(15)
(Nov. 1996).

1
2 d) its glyphosate-containing pesticide products or
any component thereof are “good” for the environment or
3 are “known for their environmental characteristics.”

4 * * *

5 e) glyphosate-containing pesticide products or any
component thereof are safer or less toxic than common
6 consumer products other than herbicides;

7 f) its glyphosate-containing products or any
component thereof might be classified as “practically
8 non-toxic.”

9 40. Monsanto did not alter its advertising in the same manner in any state
other than New York, and on information and belief it still has not done so today.

10 41. In 2009, France’s highest court ruled that Monsanto had not told the
11 truth about the safety of Roundup[®]. The French court affirmed an earlier
12 judgement that Monsanto had falsely advertised its herbicide Roundup[®] as
13 “biodegradable” and that it “left the soil clean.”¹⁹

14 *Classifications and Assessments of Glyphosate*

15 42. The IARC process for the classification of glyphosate followed
16 IARC’s stringent procedures for the evaluation of a chemical agent. Over time,
17 the IARC Monograph program has reviewed 980 agents. Of those reviewed, it
18

19 ¹⁹ *Monsanto Guilty in ‘False Ad’ Row*, BBC, Oct. 15, 2009, available at
<http://news.bbc.co.uk/2/hi/europe/8308903.stm>.

1 has determined 116 agents to be Group 1 (Known Human Carcinogens); 73 agents
2 to be Group 2A (Probable Human Carcinogens); 287 agents to be Group 2B
3 (Possible Human Carcinogens); 503 agents to be Group 3 (Not Classified); and
4 one agent to be Probably Not Carcinogenic.

5 43. The established procedure for IARC Monograph evaluations is
6 described in the IARC Programme's Preamble.²⁰ Evaluations are performed by
7 panels of international experts, selected on the basis of their expertise and the
8 absence of actual or apparent conflicts of interest.

9 44. One year before the Monograph meeting, the meeting is announced
10 and there is a call both for data and for experts. Eight months before the
11 Monograph meeting, the Working Group membership is selected and the sections
12 of the Monograph are developed by the Working Group members. One month
13 prior to the Monograph meeting, the call for data is closed and the various draft
14 sections are distributed among Working Group members for review and comment.
15 Finally, at the Monograph meeting, the Working Group finalizes review of all
16 literature, evaluates the evidence in each category, and completes the overall
17 evaluation. Within two weeks after the Monograph meeting, the summary of the

18 ²⁰ World Health Org., *IARC Monographs on the Evaluation of Carcinogenic*
19 *Risks to Humans: Preamble* (2006), available at
<http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

1 Working Group findings are published in *The Lancet Oncology*, and within a year
2 after the meeting, the finalized Monograph is published.

3 45. In assessing an agent, the IARC Working Group reviews the
4 following information: (a) human, experimental, and mechanistic data; (b) all
5 pertinent epidemiological studies and cancer bioassays; and (c) representative
6 mechanistic data. The studies must be publicly available and have sufficient detail
7 for meaningful review, and reviewers cannot be associated with the underlying
8 study.

9 46. In March 2015, IARC reassessed glyphosate. The summary
10 published in *The Lancet Oncology* reported that glyphosate is a Group 2A agent
11 and probably carcinogenic in humans.

12 47. On July 29, 2015, IARC issued its Monograph for glyphosate,
13 Monograph Volume 112. For Volume 112, a Working Group of 17 experts from
14 11 countries met at IARC from March 3–10, 2015 to assess the carcinogenicity of
15 certain herbicides, including glyphosate. The March meeting culminated a nearly
16 one-year review and preparation by the IARC Secretariat and the Working Group,
17 including a comprehensive review of the latest available scientific evidence.

18 According to published procedures, the Working Group considered “reports that
19
20

1 have been published or accepted for publication in the openly available scientific
2 literature” as well as “data from governmental reports that are publicly available.”

3 48. The studies considered the following exposure groups:

4 (1) occupational exposure of farmers and tree nursery workers in the United
5 States, forestry workers in Canada and Finland and municipal weed-control
6 workers in the United Kingdom; and (2) para-occupational exposure in farming
7 families.

8 49. Glyphosate was identified as the second-most used household
9 herbicide in the United States for weed control between 2001 and 2007 and the
10 most heavily used herbicide in the world in 2012.

11 50. Exposure pathways are identified as air (especially during spraying),
12 water, and food. Community exposure to glyphosate is widespread and found in
13 soil, air, surface water, and groundwater, as well as in food.

14 51. The assessment of the IARC Working Group identified several case
15 control studies of occupational exposure in the United States, Canada, and
16 Sweden. These studies show a human health concern from agricultural and other
17 work-related exposure to glyphosate.

1 52. The IARC Working Group found an increased risk between exposure
2 to glyphosate and NHL and several subtypes of NHL, and the increased risk
3 persisted after adjustment for other pesticides.

4 53. The IARC Working Group also found that glyphosate caused DNA
5 and chromosomal damage in human cells. One study in community residents
6 reported increases in blood markers of chromosomal damage (micronuclei) after
7 glyphosate formulations were sprayed.

8 54. In male CD-1 mice, glyphosate induced a positive trend in the
9 incidence of a rare tumor: renal tubule carcinoma. A second study reported a
10 positive trend for haemangiosarcoma in male mice. Glyphosate increased
11 pancreatic islet-cell adenoma in male rats in two studies. A glyphosate
12 formulation promoted skin tumors in an initiation-promotion study in mice.

13 55. The IARC Working Group also noted that glyphosate has been
14 detected in the urine of agricultural workers, indicating absorption. Soil microbes
15 degrade glyphosate to aminomethylphosphoric acid (AMPA). Blood AMPA
16 detection after exposure suggests intestinal microbial metabolism in humans.

17 56. The IARC Working Group further found that glyphosate and
18 glyphosate formulations induced DNA and chromosomal damage in mammals,
19 and in human and animal cells in utero.

20

1 57. The IARC Working Group also noted genotoxic, hormonal, and
2 enzymatic effects in mammals exposed to glyphosate.²¹ Essentially, glyphosate
3 inhibits the biosynthesis of aromatic amino acids, which leads to several metabolic
4 disturbances, including the inhibition of protein and secondary product
5 biosynthesis and general metabolic disruption.

6 58. The IARC Working Group also reviewed an Agricultural Health
7 Study, consisting of a prospective cohort of 57,311 licensed pesticide applicators
8 in Iowa and North Carolina.²² While this study differed from others in that it was
9 based on a self-administered questionnaire, the results support an association
10 between glyphosate exposure and multiple myeloma, hairy cell leukemia (HCL),
11 and chronic lymphocytic leukemia (CLL), in addition to several other cancers.

12 ***Other Earlier Findings About Glyphosate's Dangers to Human Health***

13 59. The EPA has a technical fact sheet, as part of its Drinking Water and
14 Health, National Primary Drinking Water Regulations publication, relating to
15

16 ²¹ Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion,*
17 *Malathion, Diazinon & Glyphosate, supra* at 77.

18 ²² Anneclaire J. De Roos et al., *Cancer Incidence Among Glyphosate-*
Exposed Pesticide Applicators in the Agricultural Health Study, 113 *Env'tl Health*
19 *Perspectives* 49–54 (2005), available at
20 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253709/pdf/ehp0113-000049.pdf>.

1 glyphosate. This technical fact sheet predates IARC's March 20, 2015 evaluation.

2 The fact sheet describes the release patterns for glyphosate as follows:

3 **Release Patterns**

4 Glyphosate is released to the environment in its use
5 as a herbicide for controlling woody and herbaceous
6 weeds on forestry, right-of-way, cropped and non-cropped
7 sites. These sites may be around water and in wetlands.

8 It may also be released to the environment during
9 its manufacture, formulation, transport, storage, disposal
10 and cleanup, and from spills. Since glyphosate is not a
11 listed chemical in the Toxics Release Inventory, data on
12 releases during its manufacture and handling are not
13 available.

14 Occupational workers and home gardeners may be
15 exposed to glyphosate by inhalation and dermal contact
16 during spraying, mixing, and cleanup. They may also be
17 exposed by touching soil and plants to which glyphosate
18 was applied. Occupational exposure may also occur
19 during glyphosate's manufacture, transport storage, and
20 disposal.²³

60. In 1995, the Northwest Coalition for Alternatives to Pesticides
reported that in California, the state with the most comprehensive program for

²³ U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate, supra.*

1 reporting of pesticide-caused illness, glyphosate was the third most commonly-
2 reported cause of pesticide illness among agricultural workers.²⁴

3 ***The Toxicity of Other Ingredients in Roundup®***

4 61. In addition to the toxicity of the active ingredient, glyphosate, several
5 studies support the hypothesis that the glyphosate-based formulation in
6 Defendant's Roundup® products is more dangerous and toxic than glyphosate
7 alone. Indeed, as early as 1991, available evidence demonstrated that glyphosate
8 formulations were significantly more toxic than glyphosate alone.²⁵

9 62. In 2002, a study by Julie Marc, entitled "Pesticide Roundup Provokes
10 Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation," revealed
11 that Roundup® causes delays in the cell cycles of sea urchins but that the same
12 concentrations of glyphosate alone were ineffective and did not alter cell cycles.²⁶

13
14 ²⁴ Caroline Cox, *Glyphosate, Part 2: Human Exposure and Ecological*
15 *Effects*, 15 J. PESTICIDE REFORM 4 (1995); W.S. Peas et al., *Preventing pesticide-*
16 *related illness in California agriculture: Strategies and priorities. Environmental*
17 *Health Policy Program Report*, Univ. of Cal. School of Public Health, Calif. Policy
18 Seminar (1993).

19 ²⁵ Martinez, T.T. and K. Brown, *Oral and pulmonary toxicology of the*
20 *surfactant used in Roundup herbicide*, PROC. WEST. PHARMACOL. SOC. 34:43-46
(1991).

²⁶ Julie Marc, et al., *Pesticide Roundup Provokes Cell Division Dysfunction*
at the Level of CDK1/Cyclin B Activation, 15 CHEM. RES. TOXICOL. 326–331
(2002), available at <http://pubs.acs.org/doi/full/10.1021/tx015543g>.

1 63. A 2004 study by Marc and others, entitled “Glyphosate-based
2 pesticides affect cell cycle regulation,” demonstrated a molecular link between
3 glyphosate-based products and cell cycle dysregulation. The researchers noted
4 that “cell-cycle dysregulation is a hallmark of tumor cells and human cancer.
5 Failure in the cell-cycle checkpoints leads genomic instability and subsequent
6 development of cancers from the initial affected cell.” Further, “[s]ince cell cycle
7 disorders such as cancer result from dysfunction of a unique cell, it was of interest
8 to evaluate the threshold dose of glyphosate affecting the cells.”²⁷

9 64. In 2005, a study by Francisco Peixoto, entitled “Comparative effects
10 of the Roundup and glyphosate on mitochondrial oxidative phosphorylation,”
11 demonstrated that Roundup[®]’s effects on rat liver mitochondria are far more toxic
12 than equal concentrations of glyphosate alone. The Peixoto study further
13 suggested that the harmful effects of Roundup[®] on mitochondrial bioenergetics
14 could not be exclusively attributed to glyphosate but could be the result of other
15 chemicals, such as the surfactant POEA, or in the alternative, due to a potential
16
17

18 ²⁷ Julie Marc, et al., *Glyphosate-based pesticides affect cell cycle*
19 *regulation*, 96 BIOLOGY OF THE CELL 245, 245-249 (2004), available at
20 <http://onlinelibrary.wiley.com/doi/10.1016/j.biolcel.2003.11.010/epdf>.

1 synergic effect between glyphosate and other ingredients in the Roundup[®]
2 formulation.²⁸

3 65. In 2009, Nora Benachour and Gilles-Eric Seralini published a study
4 examining the effects of Roundup[®] and glyphosate on human umbilical,
5 embryonic, and placental cells. The study tested dilution levels of Roundup[®] and
6 glyphosate that were far below agricultural recommendations, corresponding with
7 low levels of residue in food. The researchers ultimately concluded that supposed
8 “inert” ingredients, and possibly POEA, alter human cell permeability and amplify
9 toxicity of glyphosate alone. The researchers further suggested that assessments
10 of glyphosate toxicity should account for the presence of adjuvants or additional
11 chemicals used in the formulation of the complete pesticide. The study confirmed
12 that the adjuvants present in Roundup[®] are not, in fact, inert and that Roundup[®] is
13 potentially far more toxic than its active ingredient glyphosate alone.²⁹

14
15 ²⁸ Francisco Peixoto, *Comparative effects of the Roundup and glyphosate on*
16 *mitochondrial oxidative phosphorylation*, 61 CHEMOSPHERE 1115, 1122 (2005),
17 *available at*
https://www.researchgate.net/publication/7504567_Comparative_effects_of_the_Roundup_and_glyphosate_on_mitochondrial_oxidative_phosphorylation.

18 ²⁹ Nora Benachour, et al., *Glyphosate Formulations Induce Apoptosis and*
19 *Necrosis in Human Umbilical, Embryonic, and Placental Cells*, 22 CHEM. RES.
20 *TOXICOL.* 97-105 (2008), *available at*
<http://big.assets.huffingtonpost.com/france.pdf>.

1 66. The results of these studies were at all times available to Defendant.
2 Defendant thus knew or should have known that Roundup[®] is more toxic than
3 glyphosate alone and that safety studies of Roundup[®], Roundup's adjuvants and
4 "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiff
5 from Roundup[®].

6 67. Despite its knowledge that Roundup[®] is considerably more dangerous
7 than glyphosate alone, Defendant continued to promote Roundup[®] as safe.

8 ***Recent Worldwide Bans on Roundup[®]/Glyphosate***

9 68. Several countries around the world have instituted bans on the sale of
10 Roundup[®] and other glyphosate-containing herbicides, both before and since
11 IARC first announced its assessment for glyphosate in March 2015, and more
12 countries undoubtedly will follow suit as the dangers of the use of Roundup[®]
13 become more widely known. The Netherlands issued a ban on all glyphosate-
14 based herbicides in April 2014, including Roundup[®], which will take effect by the
15 end of 2015. In issuing the ban, the Dutch Parliament member who introduced the
16 successful legislation stated: "Agricultural pesticides in user-friendly packaging
17 are sold in abundance to private persons. In garden centers, Roundup[®] is
18 promoted as harmless, but unsuspecting customers have no idea what the risks of
19
20

1 this product are. Especially children are sensitive to toxic substances and should
2 therefore not be exposed to it.”³⁰

3 69. The Brazilian Public Prosecutor in the Federal District requested that
4 the Brazilian Justice Department suspend the use of glyphosate.³¹

5 70. France banned the private sale of Roundup[®] and glyphosate
6 following the IARC assessment for Glyphosate.³²

7 71. Bermuda banned both the private and commercial sale of
8 glyphosates, including Roundup[®]. The Bermuda government explained its ban as
9
10

11 ³⁰ *Holland’s Parliament Bans Glyphosate Herbicides*, The Real Agenda,
12 April 14, 2014, available at <http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/>.

13 ³¹ Christina Sarich, *Brazil’s Public Prosecutor Wants to Ban Monsanto’s*
14 *Chemicals Following Recent Glyphosate-Cancer Link*, GLOBAL RESEARCH, May
15 14, 2015, available at <http://www.globalresearch.ca/brazils-public-prosecutor-wants-to-ban-monsantos-chemicals-following-recent-glyphosate-cancer-link/5449440>; see Ministério Público Federal, *MPF/DF reforça pedido para que glifosato seja banido do mercado nacional*, April, 14, 2015, available at
16 http://noticias.pgr.mpf.mp.br/noticias/noticias-do-site/copy_of_meio-ambiente-e-patrimonio-cultural/mpf-df-reforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional.
17

18 ³² Zoe Schlanger, *France Bans Sales of Monsanto’s Roundup in Garden*
19 *Centers, 3 Months After U.N. Calls it ‘Probable Carcinogen’*, NEWSWEEK, June
20 15, 2015, available at <http://www.newsweek.com/france-bans-sale-monsantos-roundup-garden-centers-after-un-names-it-probable-343311>.

1 follows: “Following a recent scientific study carried out by a leading cancer
2 agency, the importation of weed spray ‘Roundup’ has been suspended.”³³

3 72. The Sri Lankan government banned the private and commercial use
4 of glyphosate, particularly out of concern that glyphosate has been linked to fatal
5 kidney disease in agricultural workers.³⁴

6 73. The government of Colombia announced its ban on using Roundup[®]
7 and glyphosate to destroy illegal plantations of coca, the raw ingredient for
8 cocaine, because of the WHO’s finding that glyphosate is probably carcinogenic.³⁵

9 ***Proposition 65 Listing***

10 74. On September 4, 2015, California’s Office of Environmental Health
11 Hazard Assessment (“OEHHA”) published a notice of intent to include glyphosate
12
13

14 ³³ *Health Minister: Importation of Roundup Weed Spray Suspended*, Today
15 in Bermuda, May, 11 2015, available at
16 [http://www.todayinbermuda.com/news/health/item/1471-health-minister-
importation-of-roundup-weed-spray-suspended](http://www.todayinbermuda.com/news/health/item/1471-health-minister-importation-of-roundup-weed-spray-suspended).

17 ³⁴ *Sri Lanka’s New President Puts Immediate Ban on Glyphosate
Herbicides*, Sustainable Pulse, May 25, 2015, available at
18 [http://sustainablepulse.com/2015/05/25/sri-lankas-new-president-puts-immediate-
ban-on-glyphosate-herbicides/#.VeduYk3bKAw](http://sustainablepulse.com/2015/05/25/sri-lankas-new-president-puts-immediate-ban-on-glyphosate-herbicides/#.VeduYk3bKAw).

19 ³⁵ *Columbia to ban coca spraying herbicide glyphosate*, BBC, May 10,
20 2015, available at <http://www.bbc.com/news/world-latin-america-32677411>.

1 on the state's list of known carcinogens under Proposition 65.³⁶ California's Safe
 2 Drinking Water and Toxic Enforcement Act of 1986 (informally known as
 3 "Proposition 65"), requires the state to maintain and, at least once a year, revise
 4 and republish a list of chemicals "known to the State of California to cause cancer
 5 or reproductive toxicity."³⁷ The OEHHA determined that glyphosate met the
 6 criteria for the listing mechanism under the Labor Code following IARC's
 7 assessment of the chemical.³⁸

8 75. The listing process under the Labor Code is essentially automatic.
 9 The list of known carcinogens, at a minimum, must include substances identified
 10 by reference in Labor Code § 6382(b)(1). That section of the Labor Code
 11 identifies "[s]ubstances listed as human or animal carcinogens by the International
 12

13 ³⁶ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment,
 14 Notice of Intent to List Chemicals by the Labor Code Mechanism:
 15 Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015),
 16 http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf.

17 ³⁷ *Frequently Asked Questions*, STATE OF CAL. DEP'T OF JUSTICE, OFFICE OF
 18 THE ATTORNEY GENERAL, <http://oag.ca.gov/prop65/faq> (last visited April 19,
 19 2016).

20 ³⁸ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment,
 Notice of Intent to List Chemicals by the Labor Code Mechanism:
 Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015),
http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf

1 Agency for Research on Cancer (IARC).” IARC’s classification of glyphosate as
2 a Group 2A chemical (“probably carcinogenic to humans”) therefore triggered the
3 listing.

4 76. A business that deploys a listed chemical in its products must provide
5 “clear and reasonable warnings” to the public prior to exposure to the chemical.
6 To be clear and reasonable, a warning must “(1) clearly communicate that the
7 chemical is known to cause cancer, and/or birth defects or other reproductive
8 harm; and (2) effectively reach the person before exposure.”³⁹ The law also
9 prohibits the discharge of listed chemicals into drinking water.

10 77. Monsanto disputed the listing decision and, in January 2016, filed a
11 lawsuit against OEHHA and the agency’s acting director, Lauren Zeise, in
12 California state court, seeking declaratory and injunctive relief to prevent OEHHA
13 from listing glyphosate.⁴⁰

16 ³⁹ *Frequently Asked Questions*, STATE OF CAL. DEPARTMENT OF JUSTICE,
OFFICE OF THE ATTORNEY GENERAL, *supra*.

17 ⁴⁰ Monsanto Company’s Verified Petition for Writ of Mandate and
18 Complaint for Preliminary and Permanent Injunctive and Declaratory Relief,
Monsanto Co. v. Office of the Env’tl Health Hazard Assessment, et al., No. 16-
19 CECG-00183 (Cal. Super. Ct.) *available at*
<http://www.monsanto.com/files/documents/monvoehha.pdf>.

1 78. Monsanto alleged that OEHHA’s exclusive reliance on the IARC
2 decision signified that “OEHHA effectively elevated the determination of an ad
3 hoc committee of an unelected, foreign body, which answers to no United States
4 official (let alone any California state official), over the conclusions of its own
5 scientific experts.”⁴¹ Monsanto further alleged that the Labor Code listing
6 mechanism presented various constitutional violations because it “effectively
7 empowers an unelected, undemocratic, unaccountable, and foreign body to make
8 laws applicable in California.”⁴² Among other things, Monsanto argued that
9 Proposition 65’s requirement to provide a “clear and reasonable warning” to
10 consumers that the chemical is a known carcinogen would damage its reputation
11 and violate its First Amendment rights.⁴³

12 79. The case remains pending.

13 ***EFSA Report on Glyphosate***

14 80. On November 12, 2015, the European Food Safety Authority
15 (EFSA), the European Union’s primary agency for food safety, reported on its
16
17

18 ⁴¹ *Id.* at 2.

19 ⁴² *Id.* at 3.

20 ⁴³ *Id.*

1 evaluation of the Renewal Assessment Report (RAR) on glyphosate.⁴⁴ The
2 Rapporteur Member State assigned to glyphosate, the German Federal Institute for
3 Risk Assessment (BfR), had produced the RAR as part of the renewal process for
4 glyphosate in the EU.

5 81. BfR sent its draft RAR to EFSA and the RAR underwent a peer
6 review process by EFSA, other member states, and industry groups. As part of the
7 on-going peer review of Germany's reevaluation of glyphosate, EFSA had also
8 received a second mandate from the European Commission to consider IARC's
9 findings regarding the potential carcinogenicity of glyphosate and glyphosate-
10 containing products.

11 82. Based on a review of the RAR, which included data from industry-
12 submitted unpublished studies, EFSA sent its own report ("Conclusion") to the
13 European Commission, finding that "glyphosate is unlikely to pose a carcinogenic
14 hazard to humans and the evidence does not support classification with regard to
15 its carcinogenic potential according to Regulation (EC) No 1272/2008."⁴⁵ EFSA
16

17 ⁴⁴ European Food Safety Auth., Conclusion on the peer review of the
18 pesticide risk assessment of the active substance glyphosate, *available at*
19 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf.

20 ⁴⁵ *Id.*

1 therefore disagreed with IARC: glyphosate was not genotoxic and did not present
2 a carcinogenic threat to humans.

3 83. In explaining why its results departed from IARC's conclusion,
4 EFSA drew a distinction between the EU and IARC approaches to the study and
5 classification of chemicals.⁴⁶ Although IARC examined "both glyphosate—an
6 active substance—and glyphosate-based formulations, grouping all formulations
7 regardless of their composition," EFSA explained that it considered only
8 glyphosate and that its assessment focuses on "each individual chemical, and each
9 marketed mixture separately."⁴⁷ IARC, on the other hand, "assesses generic
10 agents, including groups of related chemicals, as well as occupational or
11 environmental exposure, and cultural or behavioural practices."⁴⁸ EFSA accorded
12 greater weight to studies conducted with glyphosate alone than studies of
13 formulated products.⁴⁹

14 84. EFSA went further and noted:
15

16 ⁴⁶ EFSA Fact Sheet: Glyphosate, EFSA
17 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

18 ⁴⁷ *Id.*

19 ⁴⁸ *Id.*

20 ⁴⁹ *Id.*

1 [A]lthough some studies suggest that certain glyphosate-
2 based formulations may be genotoxic (i.e. damaging to
3 DNA), others that look solely at the active substance
4 glyphosate do not show this effect. It is likely, therefore,
5 that *the genotoxic effects observed in some glyphosate-*
6 *based formulations are related to the other constituents*
7 *or “co-formulants”*. Similarly, certain glyphosate-based
8 formulations display higher toxicity than that of the active
ingredient, presumably because of the presence of co-
formulants. In its assessment, *EFSA proposes that the*
9 *toxicity of each pesticide formulation and in particular*
10 *its genotoxic potential should be further considered and*
11 *addressed by Member State authorities while they re-*
12 *assess uses of glyphosate-based formulations in their*
13 *own territories.*⁵⁰

14 85. Notwithstanding its conclusion, EFSA did set exposure levels for
15 glyphosate. Specifically, EFSA proposed an acceptable daily intake (ADI) of 0.5
16 mg/kg of body weight per day; an acute reference dose (ARfD) of 0.5 mg/kg of
17 body weight; and an acceptable operator exposure level (AOEL) of 0.1 mg/kg bw
18 per day.⁵¹

19 *Leading Scientists Dispute EFSA’s Conclusion*

20 86. On November 27, 2015, 96 independent academic and governmental
scientists from around the world submitted an open letter to the EU health

⁵⁰ *Id.*

⁵¹ European Food Safety Auth., Conclusion on the peer review of the
pesticide risk assessment of the active substance glyphosate, *supra*.

1 commissioner, Vytenis Andriukaitis.⁵² The scientists expressed their strong
2 concerns and urged the commissioner to disregard the “flawed” EFSA report,
3 arguing that “the BfR decision is not credible because it is not supported by the
4 evidence and it was not reached in an open and transparent manner.”⁵³

5 87. Signatories to the letter included Dr. Christopher J. Portier, Ph.D.,
6 and other renowned international experts in the field, some of whom were part of
7 the IARC Working Group assigned to glyphosate.

8 88. In an exhaustive and careful examination, the scientists scrutinized
9 EFSA’s conclusions and outlined why the IARC Working Group decision was “by
10 far the more credible”:

11 The IARC WG decision was reached relying on open and
12 transparent procedures by independent scientists who
13 completed thorough conflict-of-interest statements and
14 were not affiliated or financially supported in any way by
15 the chemical manufacturing industry. It is fully referenced
and depends entirely on reports published in the open,
peer-reviewed biomedical literature. It is part of a long
tradition of deeply researched and highly credible reports
on the carcinogenicity of hundreds of chemicals issued

16 ⁵² Letter from Christopher J. Portier et al. to Commission Vytenis
17 Andriukaitis, Open letter: Review of the Carcinogenicity of Glyphosate by EFSA
18 and BfR (Nov. 27, 2015), <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>; <http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller>.

19 ⁵³ *Id.*

1 over the past four decades by IARC and used today by
2 international agencies and regulatory bodies around the
3 world as a basis for risk assessment, regulation and public
4 health policy.⁵⁴

5 89. With respect to human data, the scientists pointed out that EFSA
6 agreed with IARC that there was “*limited evidence* of carcinogenicity” for non-
7 Hodgkin lymphoma, but EFSA nonetheless dismissed an association between
8 glyphosate exposure and carcinogenicity. IARC applies three levels of evidence
9 in its analyses of human data, including sufficient evidence and limited evidence.
10 EFSA’s ultimate conclusion that “there was no unequivocal evidence for a clear
11 and strong association of NHL with glyphosate” was misleading because it was
12 tantamount to IARC’s highest level of evidence: “sufficient evidence,” which
13 means that a causal relationship has been established. However, the scientists
14 argued, “[l]egitimate public health concerns arise when ‘causality is credible,’ i.e.,
15 when there is *limited evidence*.”⁵⁵

16 90. Among its many other deficiencies, EFSA’s conclusions regarding
17 animal carcinogenicity data were “scientifically unacceptable,” particularly in
18 BfR’s use of historical control data and in its trend analysis. Indeed, BfR’s

19 ⁵⁴ *Id.*

20 ⁵⁵ *Id.*

1 analysis directly contradicted the Organisation for Economic Co-operation and
2 Development (“OECD”) testing guidelines while citing and purporting to follow
3 those same guidelines. For instance, the EFSA report dismisses observed trends in
4 tumor incidence “because there are no individual treatment groups that are
5 significantly different from controls and because the maximum observed response
6 is reportedly within the range of the historical control data.” However, according
7 to the scientists, concurrent controls are recommended over historical controls in
8 all guidelines, scientific reports, and publications, and, if it is employed, historical
9 control data “should be from studies in the same timeframe, for the same exact
10 animal strain, preferably from the same laboratory or the same supplier and
11 preferably reviewed by the same pathologist.” BfR’s use of historical control data
12 violated these precautions: “only a single study used the same mouse strain as the
13 historical controls, but was reported more than 10 years after the historical control
14 dataset was developed.” Further deviating from sound scientific practices, the
15 data used by the BfR came from studies in seven different laboratories. The
16 scientists concluded:

17 BfR reported seven positive mouse studies with three
18 studies showing increases in renal tumors, two with
19 positive findings for hemangiosarcomas, and two with
20 positive findings for malignant lymphomas. BfR
additionally reported two positive findings for tumors in
rats. Eliminating the inappropriate use of historical data,

1 the unequivocal conclusion is that these are not negative
2 studies, but in fact document the carcinogenicity of
glyphosate in laboratory animals.⁵⁶

3 91. The letter also critiqued the EFSA report's lack of transparency and
4 the opacity surrounding the data cited in the report: "citations for almost all of the
5 references, even those from the open scientific literature, have been redacted from
6 the document" and "there are no authors or contributors listed for either document,
7 a requirement for publication in virtually all scientific journals." Because BfR
8 relied on unpublished, confidential industry-provided studies, it is "impossible for
9 any scientist not associated with BfR to review this conclusion with scientific
10 confidence."⁵⁷

11 92. On March 3, 2016, the letter was published in the Journal of
12 Epidemiology & Community Health.⁵⁸

13 ***Statement of Concern Regarding Glyphosate-Based Herbicides***
14

15 ⁵⁶ *Id.*

16 ⁵⁷ *Id.*

17 ⁵⁸ Christopher J. Portier, et al., *Differences in the carcinogenic evaluation of*
18 *glyphosate between the International Agency for Research on Cancer (IARC) and*
the European Food Safety Authority (EFSA), JOURNAL OF EPIDEMIOLOGY &
19 CMTY. HEALTH, Mar. 3, 2016, available at
<http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full>.

93. On February 17, 2016, a consensus statement published in the journal *Environmental Health*, entitled “Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement,” assessed the safety of glyphosate-based herbicides (GBHs).⁵⁹ The paper’s “focus is on the unanticipated effects arising from the worldwide increase in use of GBHs, coupled with recent discoveries about the toxicity and human health risks stemming from use of GBHs.”⁶⁰ The researchers drew seven factual conclusions about GBHs:

1. GBHs are the most heavily applied herbicide in the world and usage continues to rise;
2. Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions;
3. The half-life of glyphosate in water and soil is longer than previously recognized;
4. Glyphosate and its metabolites are widely present in the global soybean supply;
5. Human exposures to GBHs are rising;

⁵⁹ John P. Myers, et al, *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, *Environmental Health* (2016), available at <http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>.

⁶⁰ *Id.*

1 6. Glyphosate is now authoritatively classified as a
2 probable human carcinogen; and

3 7. Regulatory estimates of tolerable daily intakes for
4 glyphosate in the United States and European
5 Union are based on outdated science.⁶¹

6 94. The researchers noted that GBH use has increased approximately
7 100-fold since the 1970s. Further, far from posing a limited hazard to vertebrates,
8 as previously believed, two decades of evidence demonstrated that “several
9 vertebrate pathways are likely targets of action, including hepatorenal damage,
10 effects on nutrient balance through glyphosate chelating action and endocrine
11 disruption.”⁶²

12 95. The paper attributes uncertainties in current assessments of
13 glyphosate formulations to the fact that “[t]he full list of chemicals in most
14 commercial GBHs is protected as ‘commercial business information,’ despite the
15 universally accepted relevance of such information to scientists hoping to conduct
16 an accurate risk assessment of these herbicide formulations.” Further, the
17 researchers argue, “[t]he distinction in regulatory review and decision processes
18 between ‘active’ and ‘inert’ ingredients has no toxicological justification, given

19 ⁶¹ *Id.*

20 ⁶² *Id.*

1 increasing evidence that several so-called ‘inert’ adjuvants are toxic in their own
2 right.”⁶³

3 96. Among various implications, the researchers conclude that “existing
4 toxicological data and risk assessments are not sufficient to infer that GBHs, as
5 currently used, are safe.” Further, “GBH-product formulations are more potent, or
6 toxic, than glyphosate alone to a wide array of non-target organisms including
7 mammals, aquatic insects, and fish.” Accordingly, “risk assessments of GBHs
8 that are based on studies quantifying the impacts of glyphosate alone
9 underestimate both toxicity and exposure, and thus risk.” The paper concludes
10 that this “shortcoming has repeatedly led regulators to set inappropriately high
11 exposure thresholds.”⁶⁴

12 97. The researchers also critique the current practice of regulators who
13 largely rely on “unpublished, non-peer reviewed data generated by the registrants”
14 but ignore “published research because it often uses standards and procedures to
15 assess quality that are different from those codified in regulatory agency data
16 requirements, which largely focus on avoiding fraud.” In the researchers’ view,
17

18 ⁶³ *Id.*

19 ⁶⁴ *Id.*

1 “[s]cientists independent of the registrants should conduct regulatory tests of
2 GBHs that include glyphosate alone, as well as GBH-product formulations.”⁶⁵

3 98. The researchers also call for greater inclusion of GBHs in
4 government-led toxicology testing programs:

5 [A] fresh and independent examination of GBH toxicity
6 should be undertaken, and . . . this re-examination be
7 accompanied by systematic efforts by relevant agencies to
8 monitor GBH levels in people and in the food supply,
9 none of which are occurring today. The U.S. National
10 Toxicology Program should prioritize a thorough
11 toxicological assessment of the multiple pathways now
12 identified as potentially vulnerable to GBHs.⁶⁶

13 99. The researchers suggest that, in order to fill the gap created by an
14 absence of government funds to support research on GBHs, regulators could adopt
15 a system through which manufacturers fund the registration process and the
16 necessary testing:

17 “[W]e recommend that a system be put in place through
18 which manufacturers of GBHs provide funds to the
19 appropriate regulatory body as part of routine registration
20 actions and fees. Such funds should then be transferred to
appropriate government research institutes, or to an
agency experienced in the award of competitive grants. In
either case, funds would be made available to independent
scientists to conduct the appropriate long-term (minimum

⁶⁵ *Id.*

⁶⁶ *Id.*

1 was harmless.⁶⁹ The paper quoted the Swedish environment minister, Åsa
 2 Romson, as stating: “We won’t take risks with glyphosate and we don’t think that
 3 the analysis done so far is good enough. We will propose that no decision is taken
 4 until further analysis has been done and the Efsa scientists have been more
 5 transparent about their considerations.”⁷⁰

6 104. The Netherlands argued that relicensing should be placed on hold
 7 until after a separate evaluation of glyphosate’s toxicity can be conducted.⁷¹
 8 Leading up to the vote, Italy joined the other EU states in opposing the license
 9 renewal, citing health concerns.⁷²

10 105. On June 6, 2016, Member States voted but failed to reach a qualified
 11 majority in favor or against the re-authorization of glyphosate.⁷³

13 ⁶⁹ Arthur Neslen, *EU states rebel against plans to relicense weedkiller*
 14 *glyphosate*, THE GUARDIAN, Mar. 4, 2016, available at
[http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-](http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate)
[plans-to-relicense-weedkiller-glyphosate.](http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate)

15 ⁷⁰ *Id.*

16 ⁷¹ Arthur Neslen, *Vote on Controversial weedkiller’s European licence*
 17 *postponed*, THE GUARDIAN, Mar. 8, 2016, available at
[http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-](http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate)
[weedkiller-licence-postponed-glyphosate.](http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate)

18 ⁷² *Id.*

19 ⁷³ Manon Flausch, *Commission prolongs glyphosate license by 18 months*,
 20 EURACTIV, June 29, 2016, available at

106. On June 29, 2016, the EU Commission extended the European license for glyphosate for 18 months to allow the European Chemical Agency to rule on the safety of the chemical, which is expected by the end of 2017.⁷⁴

107. On July 11, 2016, the EU voted in favor of a proposal to restrict the conditions of use of glyphosate in the EU, including a ban on common co-formulant POE-tallowamine (POEA) from all glyphosate-based herbicides, including Roundup.⁷⁵

108. These restrictions, which are non-binding on the EU states, are expected to apply until the European Chemicals Agency issues an opinion on the chemical's safety.⁷⁶

Plaintiff's Exposure to Roundup[®]

<http://www.euractiv.com/section/agriculture-food/news/commission-prolongs-glyphosate-licence-by-18-months/>

⁷⁴ Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016, available at <https://www.theguardian.com/business/2016/jun/29/controversial-chemical-roundup-weedkiller-escapes-immediate-ban>

⁷⁵ Sarantis Michalopoulos, *EU agrees ban on glyphosate co-formulant*, EURACTIV, July 11, 2016, available at http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-co-formulant/?nl_ref=16562829

⁷⁶ See Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016.

1 109. Plaintiff Paul Galvan is 59 years old and lives in Bell Gardens, CA.

2 110. From 1980 through 1981, Mr. Galvan worked for the California
3 Department of General Services, in Los Angeles, CA, as a groundskeeper at state
4 buildings and facilities. He used Roundup[®] two to three times a month to control
5 for weed overgrowth around state-owned buildings and facilities. Mr. Galvan
6 used a hand pump and a backpack to spray Roundup[®]. During application, he
7 wore only jeans, a work shirt, and work boots but no protective gear.

8 111. Mr. Galvan was further exposed to Roundup[®] while working for the
9 California Department of General Services from approximately 1981 through
10 1987 in Redding, CA, and then again from 1987 through 1991 in Stockton, CA.
11 During this time, he again used Roundup[®] two to three times a month to control
12 for weed overgrowth around state-owned buildings and facilities. Again, he used
13 a backpack and hand pump sprayer to spot spray Roundup[®] while only wearing
14 jeans, a work shirt, and work boots for protection.

15 112. From 1991 through 2012, Mr. Galvan worked for the California
16 Department of Transportation in Redding, CA. Mr. Galvan applied Roundup[®]
17 year-round to control weed overgrowth along the state's highways, rest areas, and
18 land fixtures. Mr. Galvan mixed and used the concentrated formulation of
19 Roundup[®] provided by the State. From October through March every year, he
20

1 used a portable 300 to 500-gallon tank with an adjustable wand for pre-emergence
2 weed control. Then, from April through September, he also used a portable
3 backpack to spot spray weed overgrowth. During application, Mr. Galvan always
4 wore a protective suit, rubber gloves, and rubber boots. He did not wear a face
5 mask or respirator because it was not required by the Department of
6 Transportation and he was not aware that he should wear one.

7 113. In or around February 2015, Plaintiff Galvan was diagnosed with
8 NK/T-cell lymphoma, a type of NHL, at the Solace Cancer Center in Redding,
9 CA. There, Mr. Galvan underwent several cycles of chemotherapy and radiation;
10 he also underwent lumbar punctures as a preventive treatment.

11 114. Mr. Galvan is currently retired and receiving treatment at City of
12 Hope—Oncology, where he is monitored every six months by his oncologist and
13 every three months by his ear nose & throat doctor.

14 115. During the entire time that Mr. Galvan was exposed to Roundup[®], he
15 did not know that exposure to Roundup[®] was injurious to his health or the health
16 of others.

17 116. Mr. Galvan first learned that exposure to Roundup[®] can cause NHL
18 and other serious illnesses sometime after July 29, 2015, when IARC first
19 published its evaluation of glyphosate.
20

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule Tolling

117. Plaintiff had no way of knowing about the risk of serious illness associated with the use of and/or exposure to Roundup[®] and glyphosate until well after IARC released its formal assessment of glyphosate in July 2015. This is the quintessential case for tolling.

118. Within the time period of any applicable statutes of limitations, Plaintiff could not have discovered, through the exercise of reasonable diligence, that exposure to Roundup[®] and glyphosate is injurious to human health.

119. Plaintiff did not discover, and did not know of facts that would cause a reasonable person to suspect, the risks associated with the use of and/or exposure to Roundup[®] and glyphosate; nor would a reasonable and diligent investigation by him have disclosed that Roundup[®] and glyphosate would cause his illness.

120. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule with respect to Plaintiff's claims.

Fraudulent Concealment Tolling

121. All applicable statutes of limitations have also been tolled by Monsanto's knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

1 127. Plaintiff brings this strict liability claim against Defendant for
2 defective design.

3 128. At all times relevant to this litigation, Defendant engaged in the
4 business of testing, developing, designing, manufacturing, marketing, selling,
5 distributing, and promoting Roundup[®] products, which are defective and
6 unreasonably dangerous to consumers and users and other persons coming into
7 contact them, including Plaintiff, thereby placing Roundup[®] products into the
8 stream of commerce. These actions were under the ultimate control and
9 supervision of Defendant. At all times relevant to this litigation, Defendant
10 designed, researched, developed, formulated, manufactured, produced, tested,
11 assembled, labeled, advertised, promoted, marketed, sold, and distributed the
12 Roundup[®] products used by Plaintiff, and/or to which Plaintiff was exposed, as
13 described above.

14 129. At all times relevant to this litigation, Defendant's Roundup[®]
15 products were manufactured, designed, and labeled in an unsafe, defective, and
16 inherently dangerous manner that was dangerous for use by or exposure to the
17 public, and, in particular, the Plaintiff.

18 130. At all times relevant to this litigation, Defendant's Roundup[®]
19 products reached the intended consumers, handlers, and users or other persons
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1 coming into contact with these products in California and throughout the United
2 States, including Plaintiff, without substantial change in their condition as
3 designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

4 131. Defendant's Roundup[®] products, as researched, tested, developed,
5 designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold,
6 and marketed by Defendant were defective in design and formulation in that when
7 they left the hands of the Defendant's manufacturers and/or suppliers, they were
8 unreasonably dangerous and dangerous to an extent beyond that which an ordinary
9 consumer would contemplate.

10 132. Defendant's Roundup[®] products, as researched, tested, developed,
11 designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold,
12 and marketed by Defendant were defective in design and formulation in that when
13 they left the hands of Defendant's manufacturers and/or suppliers, the foreseeable
14 risks associated with these products' reasonably foreseeable uses exceeded the
15 alleged benefits associated with their design and formulation.

16 133. Therefore, at all times relevant to this litigation, Defendant's
17 Roundup[®] products, as researched, tested, developed, designed, licensed,
18 manufactured, packaged, labeled, distributed, sold and marketed by Defendant,
19 were defective in design and formulation, in one or more of the following ways:
20

1 a. When placed in the stream of commerce, Defendant's
2 Roundup[®] products were defective in design and formulation, and,
3 consequently, dangerous to an extent beyond that which an ordinary
4 consumer would contemplate.

5 b. When placed in the stream of commerce, Defendant's
6 Roundup[®] products were unreasonably dangerous in that they were
7 hazardous and posed a grave risk of cancer and other serious illnesses
8 when used in a reasonably anticipated manner.

9 c. When placed in the stream of commerce, Defendant's
10 Roundup[®] products contained unreasonably dangerous design defects
11 and were not reasonably safe when used in a reasonably anticipated
12 or intended manner.

13 d. Defendant did not sufficiently test, investigate, or study
14 its Roundup[®] products and, specifically, the active ingredient
15 glyphosate.

16 e. Exposure to Roundup[®] and glyphosate-containing
17 products presents a risk of harmful side effects that outweighs any
18 potential utility stemming from the use of the herbicide.

1 f. Defendant knew or should have known at the time of
2 marketing its Roundup[®] products that exposure to Roundup[®] and
3 specifically, its active ingredient glyphosate, could result in cancer
4 and other severe illnesses and injuries.

5 g. Defendant did not conduct adequate post-marketing
6 surveillance of its Roundup[®] products.

7 h. Defendant could have employed safer alternative designs
8 and formulations.

9 134. At all times relevant to this litigation, Plaintiff used and/or was
10 exposed to the use of Defendant's Roundup[®] products in an intended or
11 reasonably foreseeable manner without knowledge of their dangerous
12 characteristics.

13 135. Plaintiff could not have reasonably discovered the defects and risks
14 associated with Roundup[®] or glyphosate-containing products before or at the time
15 of exposure.

16 136. The harm caused by Defendant's Roundup[®] products far outweighed
17 their benefit, rendering Defendant's products dangerous to an extent beyond that
18 which an ordinary consumer would contemplate. Defendant's Roundup[®] products
19 were and are more dangerous than alternative products and Defendant could have
20

1 designed its Roundup[®] products to make them less dangerous. Indeed, at the time
2 that Defendant designed its Roundup[®] products, the state of the industry's
3 scientific knowledge was such that a less risky design or formulation was
4 attainable.

5 137. At the time Roundup[®] products left Defendant's control, there was a
6 practical, technically feasible, and safer alternative design that would have
7 prevented the harm without substantially impairing the reasonably anticipated or
8 intended function of Defendant's Roundup[®] herbicides.

9 138. Defendant's defective design of Roundup[®] amounts to willful,
10 wanton, and/or reckless conduct by Defendant.

11 139. Therefore, as a result of the unreasonably dangerous condition of its
12 Roundup[®] products, Defendant is strictly liable to Plaintiff.

13 140. The defects in Defendant's Roundup[®] products were substantial and
14 contributing factors in causing Plaintiff's grave injuries, and, but for Defendant's
15 misconduct and omissions, Plaintiff would not have sustained his injuries.

16 141. As a direct and proximate result of Defendant placing its defective
17 Roundup[®] products into the stream of commerce, Plaintiff has suffered and
18 continues to suffer grave injuries, and has endured pain and discomfort, as well as
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1 economic hardship, including considerable financial expenses for medical care
2 and treatment. Plaintiff will continue to incur these expenses in the future.

3 142. WHEREFORE, Plaintiff respectfully requests that this Court enter
4 judgment in Plaintiff's favor for compensatory and punitive damages, together
5 with interest, costs herein incurred, attorneys' fees, and all such other and further
6 relief as this Court deems just and proper. Plaintiff also demands a jury trial on
7 the issues contained herein.

8 **CLAIM TWO**

9 **STRICT LIABILITY (FAILURE TO WARN)**

10 143. Plaintiff incorporates by reference each and every allegation set forth
11 in the preceding paragraphs as if fully stated herein.

12 144. Plaintiff brings this strict liability claim against Defendant for failure
13 to warn.

14 145. At all times relevant to this litigation, Defendant engaged in the
15 business of testing, developing, designing, manufacturing, marketing, selling,
16 distributing, and promoting Roundup[®] products, which are defective and
17 unreasonably dangerous to consumers, including Plaintiff, because they do not
18 contain adequate warnings or instructions concerning the dangerous characteristics
19
20

1 of Roundup[®] and specifically, the active ingredient glyphosate. These actions
2 were under the ultimate control and supervision of Defendant.

3 146. Defendant researched, developed, designed, tested, manufactured,
4 inspected, labeled, distributed, marketed, promoted, sold, and otherwise released
5 into the stream of commerce its Roundup[®] products, and in the course of same,
6 directly advertised or marketed the products to consumers and end users, including
7 Plaintiff, Plaintiff's employers, Plaintiff's co-workers, and persons responsible for
8 consumers (such as employers), and Defendant therefore had a duty to warn of the
9 risks associated with the reasonably foreseeable uses (and misuses) of Roundup[®]
10 and glyphosate-containing products.

11 147. At all times relevant to this litigation, Defendant had a duty to
12 properly test, develop, design, manufacture, inspect, package, label, market,
13 promote, sell, distribute, maintain supply, provide proper warnings, and take such
14 steps as necessary to ensure that its Roundup[®] products did not cause users and
15 consumers to suffer from unreasonable and dangerous risks. Defendant had a
16 continuing duty to warn Plaintiff of the dangers associated with Roundup[®] use and
17 exposure. Defendant, as manufacturer, seller, or distributor of chemical
18 herbicides, is held to the knowledge of an expert in the field.

1 148. At the time of manufacture, Defendant could have provided warnings
2 or instructions regarding the full and complete risks of Roundup[®] and glyphosate-
3 containing products because it knew or should have known of the unreasonable
4 risks of harm associated with the use of and/or exposure to these products.

5 149. At all times relevant to this litigation, Defendant failed to investigate,
6 study, test, or promote the safety or to minimize the dangers to users and
7 consumers of its Roundup[®] products and to those who would foreseeably use or
8 be harmed by Defendant's herbicides, including Plaintiff.

9 150. Despite the fact that Defendant knew or should have known that
10 Roundup[®] products posed a grave risk of harm, it failed to warn of the dangerous
11 risks associated with their use and exposure. The dangerous propensities of its
12 products and the carcinogenic characteristics of glyphosate, as described above,
13 were known to Defendant, or scientifically knowable to Defendant through
14 appropriate research and testing by known methods, at the time it distributed,
15 supplied, or sold the product, and not known to end users and consumers, such as
16 Plaintiff's employers.

17 151. Defendant knew or should have known that its Roundup[®] and
18 glyphosate-containing products created significant risks of serious bodily harm to
19 consumers, as alleged herein, and Defendant failed to adequately warn consumers
20

1 and reasonably foreseeable users of the risks of exposure to these products.

2 Defendant has wrongfully concealed information concerning the dangerous nature
3 of Roundup[®] and its active ingredient glyphosate, and further made false and/or
4 misleading statements concerning the safety of Roundup[®] and glyphosate.

5 152. At all times relevant to this litigation, Defendant's Roundup[®]
6 products reached the intended consumers, handlers, and users or other persons
7 coming into contact with these products throughout the United States, including
8 Plaintiff, without substantial change in their condition as designed, manufactured,
9 sold, distributed, labeled, and marketed by Defendant.

10 153. At all times relevant to this litigation, Plaintiff used and/or was
11 exposed to the use of Defendant's Roundup[®] products in their intended or
12 reasonably foreseeable manner without knowledge of their dangerous
13 characteristics.

14 154. Plaintiff could not have reasonably discovered the defects and risks
15 associated with Roundup[®] or glyphosate-containing products before or at the time
16 of Plaintiff's exposure. Plaintiff relied upon the skill, superior knowledge, and
17 judgment of Defendant.

18 155. Defendant knew or should have known that the minimal warnings
19 disseminated with its Roundup[®] products were inadequate, but it failed to
20

1 communicate adequate information on the dangers and safe use/exposure and
2 failed to communicate warnings and instructions that were appropriate and
3 adequate to render the products safe for their ordinary, intended, and reasonably
4 foreseeable uses, including agricultural and horticultural applications.

5 156. The information that Defendant did provide or communicate failed to
6 contain relevant warnings, hazards, and precautions that would have enabled
7 agricultural workers, horticultural workers and/or at-home users such as Plaintiff
8 to utilize the products safely and with adequate protection. Instead, Defendant
9 disseminated information that was inaccurate, false, and misleading and which
10 failed to communicate accurately or adequately the comparative severity, duration,
11 and extent of the risk of injuries associated with use of and/or exposure to
12 Roundup[®] and glyphosate; continued to aggressively promote the efficacy of its
13 products, even after it knew or should have known of the unreasonable risks from
14 use or exposure; and concealed, downplayed, or otherwise suppressed, through
15 aggressive marketing and promotion, any information or research about the risks
16 and dangers of exposure to Roundup[®] and glyphosate.

17 157. To this day, Defendant has failed to adequately and accurately warn
18 of the true risks of Plaintiff's injuries associated with the use of and exposure to
19 Roundup[®] and its active ingredient glyphosate, a probable carcinogen.
20

1 158. As a result of their inadequate warnings, Defendant's Roundup[®]
2 products were defective and unreasonably dangerous when they left the possession
3 and/or control of Defendant, were distributed by Defendant, and used by Plaintiff.

4 159. Defendant is liable to Plaintiff for injuries caused by its failure, as
5 described above, to provide adequate warnings or other clinically relevant
6 information and data regarding the appropriate use of its Roundup[®] products and
7 the risks associated with the use of or exposure to Roundup[®] and glyphosate.

8 160. The defects in Defendant's Roundup[®] products were substantial and
9 contributing factors in causing Plaintiff's injuries, and, but for Defendant's
10 misconduct and omissions, Plaintiff would not have sustained his injuries.

11 161. Had Defendant provided adequate warnings and instructions and
12 properly disclosed and disseminated the risks associated with its Roundup[®]
13 products, Plaintiff could have avoided the risk of developing injuries as alleged
14 herein and Plaintiff's employers could have obtained alternative herbicides.

15 162. As a direct and proximate result of Defendant placing its defective
16 Roundup[®] products into the stream of commerce, Plaintiff has suffered and
17 continues to suffer severe injuries, and has endured physical pain and discomfort,
18 as well as economic hardship, including considerable financial expenses for
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1 medical care and treatment. Plaintiff will continue to incur these expenses in the
2 future.

3 163. WHEREFORE, Plaintiff respectfully requests that this Court enter
4 judgment in Plaintiff's favor for compensatory and punitive damages, together
5 with interest, costs herein incurred, attorneys' fees, and all such other and further
6 relief as this Court deems just and proper. Plaintiff also demands a jury trial on
7 the issues contained herein.

8 **CLAIM THREE**

9 **NEGLIGENCE**

10 164. Plaintiff incorporates by reference each and every allegation set forth
11 in the preceding paragraphs as if fully stated herein.

12 165. Defendant, directly or indirectly, caused Roundup[®] products to be
13 sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

14 166. At all times relevant to this litigation, Defendant had a duty to
15 exercise reasonable care in the design, research, manufacture, marketing,
16 advertisement, supply, promotion, packaging, sale, and distribution of its
17 Roundup[®] products, including the duty to take all reasonable steps necessary to
18 manufacture, promote, and/or sell a product that was not unreasonably dangerous
19 to consumers, users, and other persons coming into contact with the product.
20

1 167. At all times relevant to this litigation, Defendant had a duty to
2 exercise reasonable care in the marketing, advertisement, and sale of its Roundup®
3 products. Defendant's duty of care owed to consumers and the general public
4 included providing accurate, true, and correct information concerning the risks of
5 using Roundup® and appropriate, complete, and accurate warnings concerning the
6 potential adverse effects of exposure to Roundup® and, in particular, its active
7 ingredient glyphosate.

8 168. At all times relevant to this litigation, Defendant knew or, in the
9 exercise of reasonable care, should have known of the hazards and dangers of
10 Roundup® and specifically, the carcinogenic properties of the chemical
11 glyphosate.

12 169. Accordingly, at all times relevant to this litigation, Defendant knew
13 or, in the exercise of reasonable care, should have known that use of or exposure
14 to its Roundup® products could cause Plaintiff's injuries and thus created a
15 dangerous and unreasonable risk of injury to the users of these products, including
16 Plaintiff.

17 170. Defendant knew or, in the exercise of reasonable care, should have
18 known that Roundup® is more toxic than glyphosate alone and that safety studies
19
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1 on Roundup[®], Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant
2 POEA were necessary to protect Plaintiff from Roundup[®].

3 171. Defendant knew or, in the exercise of reasonable care, should have
4 known that tests limited to Roundup[®]'s active ingredient glyphosate were
5 insufficient to prove the safety of Roundup[®].

6 172. Defendant also knew or, in the exercise of reasonable care, should
7 have known that users and consumers of Roundup[®] were unaware of the risks and
8 the magnitude of the risks associated with the use of and/or exposure to Roundup[®]
9 and glyphosate-containing products.

10 173. As such, Defendant breached its duty of reasonable care and failed to
11 exercise ordinary care in the design, research, development, manufacture, testing,
12 marketing, supply, promotion, advertisement, packaging, sale, and distribution of
13 its Roundup[®] products, in that Defendant manufactured and produced defective
14 herbicides containing the chemical glyphosate, knew or had reason to know of the
15 defects inherent in its products, knew or had reason to know that a user's or
16 consumer's exposure to the products created a significant risk of harm and
17 unreasonably dangerous side effects, and failed to prevent or adequately warn of
18 these risks and injuries.

1 174. Defendant failed to appropriately and adequately test Roundup[®],
2 Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant POEA to
3 protect Plaintiff from Roundup[®].

4 175. Despite its ability and means to investigate, study, and test its
5 products and to provide adequate warnings, Defendant has failed to do so. Indeed,
6 Defendant has wrongfully concealed information and has further made false
7 and/or misleading statements concerning the safety and/or exposure to Roundup[®]
8 and glyphosate.

9 176. Defendant's negligence included:

10 a. Manufacturing, producing, promoting, formulating,
11 creating, developing, designing, selling, and/or distributing its
12 Roundup[®] products without thorough and adequate pre- and post-
13 market testing;

14 b. Manufacturing, producing, promoting, formulating,
15 creating, developing, designing, selling, and/or distributing
16 Roundup[®] while negligently and/or intentionally concealing and
17 failing to disclose the results of trials, tests, and studies of exposure to
18 glyphosate, and, consequently, the risk of serious harm associated
19 with human use of and exposure to Roundup[®];
20

1 c. Failing to undertake sufficient studies and conduct
2 necessary tests to determine whether or not Roundup[®] products and
3 glyphosate-containing products were safe for their intended use in
4 agriculture, horticulture, and at-home use;

5 d. Failing to undertake sufficient studies and conduct
6 necessary tests to determine the safety of “inert” ingredients and/or
7 adjuvants contained within Roundup[®], and the propensity of these
8 ingredients to render Roundup[®] toxic, increase the toxicity of
9 Roundup[®], whether these ingredients are carcinogenic, magnify the
10 carcinogenic properties of Roundup[®], and whether or not “inert”
11 ingredients and/or adjuvants were safe for use;

12 e. Failing to use reasonable and prudent care in the design,
13 research, manufacture, formulation, and development of Roundup[®]
14 products so as to avoid the risk of serious harm associated with the
15 prevalent use of Roundup[®]/glyphosate as an herbicide;

16 f. Failing to design and manufacture Roundup[®] products
17 so as to ensure they were at least as safe and effective as other
18 herbicides on the market;

1 g. Failing to provide adequate instructions, guidelines, and
2 safety precautions to those persons who Defendant could reasonably
3 foresee would use and/or be exposed to its Roundup[®] products;

4 h. Failing to disclose to Plaintiff, users, consumers, and the
5 general public that the use of and exposure to Roundup[®] presented
6 severe risks of cancer and other grave illnesses;

7 i. Failing to warn Plaintiff, users, consumers, and the
8 general public that the product's risk of harm was unreasonable and
9 that there were safer and effective alternative herbicides available to
10 Plaintiff and other users or consumers;

11 j. Systematically suppressing or downplaying contrary
12 evidence about the risks, incidence, and prevalence of the side effects
13 of Roundup[®] and glyphosate-containing products;

14 k. Representing that its Roundup[®] products were safe for
15 their intended use when, in fact, Defendant knew or should have
16 known that the products were not safe for their intended use;

17 l. Declining to make or propose any changes to Roundup[®]
18 products' labeling or other promotional materials that would alert the
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1 consumers and the general public of the risks of Roundup[®] and
2 glyphosate;

3 m. Advertising, marketing, and recommending the use of
4 Roundup[®] products, while concealing and failing to disclose or warn
5 of the dangers known by Defendant to be associated with or caused
6 by the use of or exposure to Roundup[®] and glyphosate;

7 n. Continuing to disseminate information to its consumers,
8 which indicate or imply that Defendant's Roundup[®] products are not
9 unsafe for use in the agricultural, horticultural industries, and/or
10 home use; and

11 o. Continuing the manufacture and sale of its products with
12 the knowledge that the products were unreasonably unsafe and
13 dangerous.

14 177. Defendant knew and/or should have known that it was foreseeable
15 that consumers and/or users, such as Plaintiff, would suffer injuries as a result of
16 Defendant's failure to exercise ordinary care in the manufacturing, marketing,
17 labeling, distribution, and sale of Roundup[®].

1 178. Plaintiff did not know the nature and extent of the injuries that could
2 result from the intended use of and/or exposure to Roundup[®] or its active
3 ingredient glyphosate.

4 179. Defendant's negligence was the proximate cause of the injuries,
5 harm, and economic losses that Plaintiff suffered, and will continue to suffer, as
6 described herein.

7 180. Defendant's conduct, as described above, was reckless. Defendant
8 regularly risks the lives of consumers and users of its products, including Plaintiff,
9 with full knowledge of the dangers of its products. Defendant has made conscious
10 decisions not to redesign, re-label, warn, or inform the unsuspecting public,
11 including Plaintiff. Defendant's reckless conduct therefore warrants an award of
12 punitive damages.

13 181. As a proximate result of Defendant's wrongful acts and omissions in
14 placing its defective Roundup[®] products into the stream of commerce without
15 adequate warnings of the hazardous and carcinogenic nature of glyphosate,
16 Plaintiff has suffered and continues to suffer severe and permanent physical and
17 emotional injuries. Plaintiff has endured pain and suffering, has suffered
18 economic losses (including significant expenses for medical care and treatment),
19 and will continue to incur these expenses in the future.

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1 severe and permanent personal injuries sustained by Plaintiff,

2 including health care costs and economic loss;

3 C. economic damages in the form of medical expenses, out-of-pocket
4 expenses, lost earnings and other economic damages in an amount to
5 be determined at trial of this action;

6 D. punitive and/or exemplary damages for the wanton, willful, fraudulent,
7 and reckless acts of the Defendant who demonstrated a complete
8 disregard and reckless indifference for the safety and welfare of the
9 general public and to the Plaintiff in an amount sufficient to punish
10 Defendant and deter future similar conduct, to the extent allowed by
11 applicable law;

12 E. pre- and post-judgment interest;

13 F. costs including reasonable attorneys' fees, court costs, and other
14 litigation expenses; and

15 G. any other relief the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all of the triable issues within this Complaint.

Dated: January 31, 2017
New York, New York

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